Filed: 08/14/06

Title: Pharmaceutical Preparation For The Oral Cavity

Preliminary Amendment Inventor: Paolo A. Veronesi

Examiner: N/A

Amendment(s) to the Claims

The following listing of claims replaces all prior versions and listings of claims in

the present application:

<u>Listing of Claims</u>:

1 (currently amended): A throat, mouth and/or gum sprayable pharmaceutical

preparation in the form of an aqueous solution comprising:

a nonsteroidal non-steroidal antiinflammatory anti-inflammatory drug

(NSAID) also having analgesic activity;

a biologically compatible buffer consisting essentially of an organic amine

selected from at least one of D-glucamine, meglumine, trometamol (tris buffer)

and a mixture thereof, in a quantity suitable for buffering the pH of the

preparation within the range specified below;

a pH within a range from 6.5 to 8.0; and

pharmaceutical grade water;

wherein the NSAID is flurbiprofen.

2 (currently amended): Use of a sprayable pharmaceutical preparation for in the

manufacture of an antiinflammatory anti-inflammatory agent for treating the mouth,

throat and/or gums, wherein the pharmaceutical composition preparation is in the form

of an aqueous solution comprising:

a nonsteroidal non-steroidal anti-inflammatory drug (NSAID) also having

analgesic activity;

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a biologically compatible buffering organic amine provided with a free or

monosubstituted amino group or a mixture thereof, in a quantity suitable for

buffering the pH of the preparation within the range specified below;

a pH within a range from 6.5 to 8.0; and

pharmaceutical grade water;

wherein the NSAID is flurbiprofen and the biologically compatible buffering

organic amine is D-glucamine, meglumine, trometamol (tris buffer) or a mixture thereof.

3 (currently amended): A pharmaceutical preparation or use according to claim 1 or

claim 2, wherein the flurbiprofen is in the form of a racemate or one of its enantiomers

selected from R-(-) flurbiprofen and S-(+) flurbiprofen.

4 (currently amended): A pharmaceutical preparation or use according to any one of

claims claim 1 to 3, which comprises wherein the flurbiprofen is present in a quantity of

from about 1.5 mg/ml to about 8.0 mg/ml, preferably about 2.5 mg/ml.

5 (currently amended): A pharmaceutical preparation or use according to any one of the

preceding claims claim 1, which has a wherein the pH of from is between about 7.0 to

and about 7.5.

6 (currently amended): A pharmaceutical preparation or use according to any one of the

preceding claims claim 1, which comprises wherein D-glucamine is present in a quantity

of from about 0.35 mg/ml to about 1.12 mg/ml; meglumine is present in a quantity of

from about 0.40 mg/ml to about 2.4 mg/ml; and/or trometamol is present in a quantity of

from about 0.10 mg/ml to about 0.75 mg/ml.

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7 (currently amended): A pharmaceutical preparation or use according to any one of the

preceding claims claim 1, which comprises wherein the buffer is present in a quantity

suitable for buffering the pH of the solution within the range of from between about 7.0

to and about 7.5.

8 (currently amended): A pharmaceutical preparation or use according to any one of the

preceding claims claim 1, which further comprises comprising:

a mild disinfectant; and/or

one or more preservatives; and

wherein:

the mild disinfectant comprises at least one of (i) cetylpyridinium chloride,

optionally in a quantity of from about 1.0 mg/ml to about 6.0 mg/ml, optimally of about

5.0 mg/ml, and (ii) glycyrrhizic acid or a salt thereof, optionally in a quantity of from

about 0.8 mg/ml to about 1.2 mg/ml, optimally of about 1.0 mg/ml; and

the preservative comprises at least one of (i) methyl p-hydroxybenzoate,

optionally in a quantity of from about 0.25 mg/ml to about 1.15 mg/ml, (ii) propyl p-

hydroxybenzoate, optionally in a quantity of from about 0.03 mg/ml to about 0.15 mg/ml,

(iii) disodium calcium edetate, optionally in a quantity of from about 0.1 mg/ml to about

1.0 mg/ml, and (iv) sodium benzoate, optionally in a quantity of from about 0.2 mg/ml to

about 5.0 mg/ml.

9 (currently amended): A pharmaceutical preparation or use according to any one of the

preceding claims claim 1, which further comprises comprising at least one further

ingredient selected from the group consisting of a viscosity agent, a sweetening agent,

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a fluidising agent, a thickening agent, a colouring agent and a natural essence of

flavouring agent.

10 (currently amended): A pharmaceutical preparation or use according to claim 9,

wherein the further ingredient is selected from the group consisting of at least one of

glycerol, sorbitol, xylitol, ethyl alcohol, castor oil 40 polyethoxylate, saccharin sodium,

acesulfame potassium, mint essence, natural mint flavour, natural peach flavour and

patent blue V-E131, E-124.

11 (currently amended): A pharmaceutical preparation or use according to any one of

claims claim 1 to 9, further comprising xylitol[,].

12 (currently amended): A pharmaceutical preparation or use according to any one of

the preceding claims claim 1, wherein the preparation is in the form of a mouthwash for

spraying, preferably with a dispensed volume for each unit dose of from about 100

microlitres (0.1 ml) to about 300 microlitres (0.3 ml), preferably of about 200 microlitres

(0.2-ml).

13 (currently amended): A pharmaceutical preparation or use according to any one of

the preceding claims claim 1, wherein the buffer is D-glucamine, meglumine, or a

mixture thereof.

14 (currently amended): A packaged pharmaceutical preparation containing the

pharmaceutical preparation defined in any one of claims according to claim 1 to 13,

wherein the preparation is equipped with a dosing pump.

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15 (currently amended): A process for the production of the pharmaceutical preparation

defined in any one of claims claim 1 to 13, which comprises comprising:

(i) dissolving preservative(s) in a solution;

(ii) dissolving the selected NSAID in water or a water/ethyl alcohol mixture

and buffering with the organic amine to the specified pH value;

(iii) adding any auxiliary ingredients to the solution of step (i), and mixing the

solution of step (i) with the solution of NSAID and organic amine from step (ii);

(iv) making up to volume (or weight) with water, if necessary, and adjusting

the pH to the prescribed value with addition of organic amine.

16 (new): A pharmaceutical preparation according to claim 1, wherein the flurbiprofen is

present in a quantity of about 2.5 mg/ml.

17 (new): A pharmaceutical preparation according to claim 12, wherein the dispensed

volume for each unit dose is about 200 microlitres (0.2 ml).

18 (new): The use according to claim 2, wherein the flurbiprofen is in the form of a

racemate or one of its enantiomers selected from R-(-) flurbiprofen and S-(+)

flurbiprofen.

19 (new): The use according to claim 2, wherein the flurbiprofen is present in a quantity

of from about 1.5 mg/ml to about 8.0 mg/ml.

20 (new): The use according to claim 2, wherein the flurbiprofen is present in a quantity

of about 2.5 mg/ml.

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21 (new): The use according to claim 2, wherein the pH of the solution is between about

7.0 and about 7.5.

22 (new): The use according to claim 2, wherein D-glucamine is present in a quantity of

from about 0.35 mg/ml to about 1.12 mg/ml; meglumine is present in a quantity of from

about 0.40 mg/ml to about 2.4 mg/ml; and/or trometamol is present in a quantity of from

about 0.10 mg/ml to about 0.75 mg/ml.

23 (new): The use according to claim 2, wherein the buffer is present in a quantity

suitable for buffering the pH of the solution within the range of between about 7.0 and

about 7.5.

24 (new): The use according to claim 2, wherein the pharmaceutical preparation further

comprises:

a mild disinfectant; and/or

one or more preservatives; and

wherein:

the mild disinfectant comprises at least one of (i) cetylpyridinium chloride,

optionally in a quantity of from about 1.0 mg/ml to about 6.0 mg/ml, optimally about 5.0

mg/ml, and (ii) glycyrrhizic acid or a salt thereof, optionally in a quantity of from about

0.8 mg/ml to about 1.2 mg/ml, optimally about 1.0 mg/ml; and

the preservative comprises at least one of (i) methyl p-hydroxybenzoate,

optionally in a quantity of from about 0.25 mg/ml to about 1.15 mg/ml, (ii) propyl p-

hydroxybenzoate, optionally in a quantity of from about 0.03 mg/ml to about 0.15 mg/ml,

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(iii) disodium calcium edetate, optionally in a quantity of from about 0.1 mg/ml to about

1.0 mg/ml, and (iv) sodium benzoate, optionally in a quantity of from about 0.2 mg/ml to

about 5.0 mg/ml.

25 (new): The use according to claim 2, wherein the pharmaceutical preparation further

comprises at least one further ingredient selected from the group consisting of a

viscosity agent, a sweetening agent, a fluidising agent, a thickening agent, a colouring

agent and a natural essence of flavouring agent.

26 (new): The use according to claim 25, wherein the further ingredient is selected from

the group consisting of at least one of glycerol, sorbitol, xylitol, ethyl alcohol, castor oil

40 polyethoxylate, saccharin sodium, acesulfame potassium, mint essence, natural mint

flavour, natural peach flavour and patent blue V-E131, E-124.

27 (new): The use according to claim 2, wherein the pharmaceutical preparation further

comprises xylitol.

28 (new): The use according to claim 2, wherein the preparation is in the form of a

mouthwash for spraying, preferably with a dispensed volume for each unit dose of from

about 100 microlitres (0.1 ml) to about 300 microlitres (0.3 ml).

29 (new): The use according to claim 28, wherein the dispensed volume for each unit

dose is about 200 microlitres (0.2 ml).

30 (new): The use according to claim 2, wherein the buffer is D-glucamine, meglumine,

or a mixture thereof.

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31 (new): The use according to claim 2, wherein the pharmaceutical preparation is supplied with a dosing pump.